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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/696,676 | 10/29/2003 | Keith L. Black | 67789-503 | 8501 |

50670 7590 06/28/2006

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| EXAMINER |
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SCHNIZER, RICHARD A

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| ART UNIT | PAPER NUMBER |
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1635

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

An amendment was received and entered on 5/2/06. Applicant's election without traverse of group II and the species of IL-2 is acknowledged. Applicant asserts that this species reads on claims 168-176, 184, 187, 191, and 200-203. However, claims 168-176 are drawn to compositions comprising a combination of an agonist of a calcium-activated potassium channel, other than bradykinin or a bradykinin analog, formulated together with a cytotoxic agent. IL-2 is not a cytotoxic agent. IL-2 is a cytokine that mediates proliferation of cells, among them cytotoxic T-cells, but it is not itself cytotoxic. As a result IL-2 does not read on claims 168-176, but instead reads on claims 184, 185, 187, and 191 which are drawn to a composition comprising a drug and a calcium-activated potassium channel agonist. Claims 200-203 do not recite or require any cytotoxic agent or drug, so the species election is not be applied to these claims.

Claims 1, 110-183, 186, 188-190, and 192-199 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/2/06.

Claims 184, 185, 187, and 191, and 200-203 are under consideration in this Office Action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35

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U.S.C. 120 as follows: Although the transmittal letter filed 10/29/03 makes clear that this application is a continuation of 09/491,500, the preliminary amendment filed 10/29/03 claiming priority to 09/491,500 does not state the relationship between the two applications. The first line of the specification should be amended to make clear the relationship between the two applications. Also, the status of 09/491,500 should be updated because it has issued as US Patent 7,018,979.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 184, 185, 187, and 191 are rejected under 35 U.S.C. 102(b) as being anticipated by Novogrodsky et al (J. Immunol. 143: 3981-3987, 1989).

Novogrodsky taught a culture of peripheral blood mononuclear cells comprising IL-2 and either Zn protoporphyrin or Sn protoporphyrin. See abstract, sentence bridging columns 1 and 2 on page 3982, page 3983, column 2, third full paragraph, Table II on page 3984, and Tables IV and V on page 3985. These protoporphyrins are considered to be calcium-activated potassium channel agonists in view of the specification as filed. See e.g. instant claim 175 The culture media is considered to be pharmaceutically acceptable solution. Absent evidence to the contrary, these cultures are in a form that could be injected or infused intravascularly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 200 and 201 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veltkamp et al (Stroke 29: 837-843, 1998).

Veltkamp taught methods of assaying the effects of NS-1619 on the vascular response to NMDA after hypoxia and ischemia. See abstract.

Veltkamp did not teach the organization of NS-1619 and NMDA into a kit. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to organize these agents into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

The text of Veltkamp, could be considered to be instructions for how to use the kit. However, it is noted that the "instructions for use" limitation does not receive patentable weight because the courts have repeatedly found that the application of particular printed matter to an old article cannot render the article patentable. For example, in the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "[w]hether the statement of intended use appears merely in the claim or in a label

on the product is immaterial so far as the question of patentability is concerned." The court in *In re Gulack* (217 USPQ 401 (1983)) found that printed matter has no patentable weight unless the printed matter affects the function of the product claimed. Also, see in *In re Ngai* (70 USPQ2D 1862 (2004)).

Claims 200 and 202 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devor et al (Am. J. Physiol. 271(5): L775-84, 1996).

Devor evaluated the effects of 1-EBIO and charybdotoxin on chloride ion secretion in T84 monolayers. See abstract.

Devor did not teach the organization of 1-EBIO into a kit. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to organize these agents into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

The text of Devor could be considered to be instructions for how to use the kit. However, it is noted that the "instructions for use" limitation does not receive patentable weight because the courts have repeatedly found that the application of particular printed matter to an old article cannot render the article patentable. For example, in the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "[w]hether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The court in *In re Gulack* (217 USPQ 401 (1983)) found that printed matter has no patentable weight

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unless the printed matter affects the function of the product claimed. Also, see in *In re Ngai* (70 USPQ2D 1862 (2004)).

Claims 200 and 203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novogrodsky et al (J. Immunol. 143: 3981-3987, 1989).

Novogrodsky taught a culture of peripheral blood mononuclear cells comprising IL-2 and either Zn protoporphyrin or Sn protoporphyrin. See abstract, sentence bridging columns 1 and 2 on page 3982, page 3983, column 2, third full paragraph, Table II on page 3984, and Tables IV and V on page 3985. These cultures are considered to be pharmaceutical compositions because they comprise all of the structural features of the claims. Absent evidence to the contrary, these cultures are in a form that could be injected or infused intravascularly.

Novogrodsky did not teach the organization of IL-2 and Zn protoporphyrin or Sn protoporphyrin into a kit. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to organize the IL-2 and Zn protoporphyrin or Sn protoporphyrin of Novogrodsky into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

The text of Novogrodsky, could be considered to be instructions for how to use the kit. However, it is noted that the "instructions for use" limitation does not receive patentable weight because the courts have repeatedly found that the application of particular printed matter to an old article cannot render the article patentable. For

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example, in the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated “[w]hether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned.” The court in *In re Gulack* (217 USPQ 401 (1983)) found that printed matter has no patentable weight unless the printed matter affects the function of the product claimed. Also, see in *In re Ngai* (70 USPQ2D 1862 (2004)).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached at (571) 272-4517. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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A handwritten signature in black ink, appearing to read 'RS', with a long horizontal line extending to the right.

Richard Schnizer, Ph.D.
Primary Examiner
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